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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,198	10/29/1999	DAVID ZAHNISER	CYM-034	6914

23639 7590 01/14/2004

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EXAMINER	
KIM, CHONG R	

ART UNIT	PAPER NUMBER
2623	13

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/430,198	ZAHNISER ET AL.	
	Examiner	Art Unit	
	Charles Kim	2623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,20,21 and 23-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,20,21 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 1999* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment and Arguments

1. Applicant's amendment filed on November 3, 2003 has been entered and made of record.

2. Applicant's arguments with respect to claims 1, 2, 5, 7, 10-14, and 20-21 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

3. The drawings are objected to because they are not of sufficient quality for publication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Referring to claim 10, the phrase "spatially locating the mark, thereby determining the spatial offset value of the mark relative to the reference coordinate value" in lines 7-8 renders the claim indefinite because it is unclear if the phrase is further limiting the step of "locating a datum mark on the sample" in line 3, or if it is an entirely separate step for locating the datum mark. It appears that applicant intended the phrase to read "spatially re-locating the mark, thereby

determining the spatial offset value of the re-located mark relative to the reference coordinate value". A similar rejection is also applicable to claim 14. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gibbs, U.S. Patent No. 5,000,554 ("Gibbs").

Referring to claim 1, Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising:

a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)

b. identifying the area of interest within the sample (col. 9, lines 30-41)

c. determining the location of the area of interest relative to the mark (col. 9, lines 41-46)

d. relocating the datum (col. 9, lines 60-66).

Gibbs further discloses that the location of the area of interest is verified when the area of interest is detected "at approximately the same location as when it was originally detected" (col. 10, lines 1-6). Gibbs fails to explicitly disclose that the location of the area of interest is verified if a dimensional error in locating the datum relative to relocating the datum is less than a

tolerance value. However, Gibbs explains that relocating the datum results in a position that is approximate to the position determined originally in locating the datum (col. 9, lines 60-65). The Examiner notes that the word "approximate" is defined by the Webster's dictionary as "nearly correct or exact". Therefore, a dimensional error is an inherent feature in determining an approximate position. Although Gibbs does not explicitly state that the location of the area of interest is verified if the dimensional error is less than a tolerance value, it would have been obvious to modify Gibbs's teachings so that the location of area of interest is verified if the dimensional error is less than a tolerance value, in order to allow the area of interest to be detected on a later occasion at approximately the same location as when it was originally detected (col. 9, line 60-col. 10, line 6), thereby resulting in highly accurate locating and relocating of microscopic objects of interest in the sample slide (col. 12, lines 65-68).

Referring to claim 2, Gibbs further discloses that identification of the area of interest within the sample comprises optically scanning the sample (col. 9, lines 30-35).

Referring to claim 3, Gibbs fails to explicitly disclose that the tolerance value is between about ten microns and one thousand microns. However, Gibbs explains that relocating the datum results in a position that is approximate to the position originally determined in locating the datum, as noted above. Therefore, although Gibbs does not explicitly teach that the tolerance value is between about ten microns and one thousand microns, it would have been obvious to have a tolerance value between ten microns and one thousand microns, in order to minimize the dimensional error and provide a highly accurate locating and relocating of microscopic objects of interest in the sample slide (col. 12, lines 65-68).

Referring to claim 5, Gibbs further discloses that the sample comprises a cytological specimen deposited on a slide (col. 6, lines 20-22).

Referring to claim 7, Gibbs further discloses that the sample is mounted on a stage (col. 4, lines 54-58).

Referring to claim 8, Gibbs fails to explicitly disclose the step of rejecting the sample if the location of the area of interest is not verified. However, Gibbs is concerned with accurately locating and relocating the area of interest in the sample slide (col. 12, lines 65-68). Therefore, it would have been obvious to reject the sample if the location of the area of interest is not verified, since a location of the area of interest that is not verified implies that the area of interest is not accurately located. The ordinary artisan would have been motivated to do so in order to obtain sample slides that include the locations of the area of interest determined accurately, thereby improving the accuracy and efficiency of the examination process.

6. Claims 4, 6, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gibbs, U.S. Patent No. 5,000,554 ("Gibbs") and Kamentsky, U.S. Patent No. 5,587,833 ("Kamentsky").

Referring to claim 4, Gibbs fails to disclose the steps of identifying a plurality of areas of interest within the sample and ranking the plurality of areas of interest in an order.

Kamentsky teaches the steps of identifying a plurality of areas of interest within a sample and ranking the plurality of areas of interest in an order (col. 8, lines 4-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and increases efficiency of the re-

examination process by providing the Pathologist with the locations of the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious to include the teachings of Kamentsky in the method of Gibbs, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

Referring to claim 6, Gibbs explains that the sample comprises a blood sample specimen (col. 6, lines 20-22), but fails to explicitly state that the area of interest within the sample comprises an abnormal cell. However, defining an area of interest within a blood sample as an abnormal cell was exceedingly well known in the art. For example, Kamentsky discloses that the area of interest within a blood sample comprises an abnormal cell (col. 1, lines 12-19).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Therefore, it would have been obvious to modify the area of interest of Gibbs so that it comprises an abnormal cell, as taught by Kamentsky, in order to utilize the method for pathological research such as the examination of cancer cells, thereby increasing the flexibility of the system (Kamentsky, col. 1, lines 12-19).

Referring to claim 9, Gibbs fails to teach the step of placing a visible indicator proximate the area of interest identified within the sample.

Kamentsky teaches the step of placing a visible indicator proximate the area of interest identified within the sample (col. 8, lines 15-18).

Gibbs and Kamentsky are both concerned with locating an area of interest within a cytological sample slide. Kamentsky's method saves time and thereby increases efficiency of the re-examination process by providing the Pathologist with visible indicators at the locations of

the areas of interest that were considered important during an initial examination (Kamentsky, col. 8, lines 22-39). Therefore, it would have been obvious modify the method of Gibbs, so that a visible indicator is placed proximate the area of interest within the sample, as taught by Kamentsky, in order to reduce the redundancy of the work required by the Pathologist, thereby enhancing the efficiency of the overall examination process.

7. Claims 10-14, 20-21, 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Gibbs, U.S. Patent No. 5,000,554 ("Gibbs") and Ortyn et al., U.S. Patent No. 5,499,097 ("Ortyn").

Referring to claim 10 as best understood, see the discussion of at least claim 1 above. Gibbs discloses a method for verifying a location of an area of interest within a sample, the method comprising:

a. locating a datum (reference) mark on the sample (col. 9, lines 12-29)

b. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6]

c. identifying the area of interest within the sample (col. 9, lines 30-41)

d. assigning a coordinate value to the location of the area of interest (col. 9, lines 30-46)

e. spatially re-locating the mark (col. 9, lines 60-66).

Gibbs further discloses that a spatial offset exists between the re-located mark relative to the originally located mark, as noted above (claim 1). However, Gibbs fails to explicitly disclose the step of determining a spatial offset value of the relocated mark relative to the reference coordinate value.

Ortyn discloses the step of locating a datum mark on the sample, assigning a reference coordinate value to a location of the mark, and spatially re-locating the mark, thereby determining a spatial offset value of the re-located mark relative to the reference coordinate value (col. 5, line 59-col. 6, line 17). Ortyn further discloses that the measured data is verified (validated) if the spatial offset value is less than a tolerance value (col. 2, lines 45-48 and col. 6, TABLE 1).

Gibbs and Ortyn are both concerned with repeatedly taking measurements utilizing a cytological imaging system (Gibbs, col. 12, lines 65-68, Ortyn, col. 6, lines 14-17). Ortyn's method ensures that the system performs above or beyond the engineered limits of the design (Ortyn, col. 1, lines 29-31). Therefore, it would have been obvious to combine the teachings of Gibbs and Ortyn, in order to maintain a high level of system performance.

Referring to claim 11, Gibbs further discloses that the step of first locating the datum mark comprises centering the mark in a field of view of an optical instrument (col. 9, lines 12-16).

Referring to claim 12, Gibbs further discloses the step of storing in the memory the coordinate value of the area of interest (col. 2, lines 40-46 and col. 6, lines 26-31).

Referring to claim 13, Gibbs further discloses the steps of:

f. transferring the sample to a review station (col. 6, lines 41-47)

g. locating the datum mark (col. 6, lines 47-52)

h. setting a coordinate system of the review station based on a location of the mark (col. 6, lines 52-68, see also col. 3, lines 1-6).

Referring to claim 14 as best understood, Gibbs discloses a method for verifying an area of interest within a cytological specimen on a slide loaded in an automated cytological imaging, the method comprising:

a. placing the slide within an optical path of the imaging system (col. 9, lines 12-16)

b. centering the datum mark on the slide within a field of view of the imaging system (col. 9, lines 12-16)

c. assigning a reference coordinate value to a location of the mark [col. 9, lines 16-20 and lines 38-46. Note that the position of the datum mark is assigned as the reference position (0, 0), since the x and y coordinates of the detected object is the coordinate position relative to the position of the datum mark, see also col. 2, line 47-col. 3, line 6].

d. storing in memory the reference coordinate value (col. 9, lines 16-20)

e. scanning the slide to identify an area of interest within the sample (col. 9, lines 30-46)

f. centering the area of interest within the field of view of the imaging system (col. 9, lines 38-41)

g. assigning a coordinate value to the area of interest (col. 9, lines 30-45)

h. returning to the reference coordinate value location (col. 9, lines 60-68)

i. spatially re-locating the mark (col. 9, lines 60-68).

Gibbs fails to explicitly disclose the step of comparing the reference coordinate value to a coordinate value resulting from spatially re-locating the mark. However, this feature was exceedingly well known in the art. For example, Ortyn discloses the step of locating a datum mark on the sample, assigning a reference coordinate value to a location of the mark, spatially re-locating the mark, and comparing the reference coordinate value to a coordinate value resulting from spatially re-locating the mark, thereby determining a spatial offset value of the mark (col. 5, line 59-col. 6, line 17). Ortyn further discloses that the measured data is verified (validated) if the spatial offset value is less than a tolerance value (col. 2, lines 45-48 and col. 6, TABLE 1).

Gibbs and Ortyn are both concerned with repeatedly taking measurements utilizing a cytological imaging system (Gibbs, col. 12, lines 65-68, Ortyn, col. 6, lines 14-17). Ortyn's method ensures that the system performs above or beyond the engineered limits of the design (Ortyn, col. 1, lines 29-31). Therefore, it would have been obvious to combine the teachings of Gibbs and Ortyn, in order to maintain a high level of system performance.

Referring to claim 20, see the rejection of at least claim 10 above. Gibbs further discloses an optical system and a stage movable relative to the optical system, at least one of the optical system and the stage being operable to position the sample in an optical path of the optical system (col. 6, lines 20-26).

Referring to claim 21, see the discussion of at least claim 5 above.

Referring to claim 23, Ortyn further discloses that the method is performed while the slide is continuously mounted within the imaging system (col. 5, lines 23-58).

Referring to claims 24 and 25, see the rejections of claims 14 and 23 above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles Kim whose telephone number is 703-306-4038. The examiner can normally be reached on Mon thru Thurs 8:30am to 6pm and alternating Fri 9:30am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on 703-308-6604. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0377.

ck
January 7, 2004

AMELIA M. AU
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